Docket No.: **1360-001**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT OPERATIONS

In re Application of:

Maxwell Gordon Group Art Unit: 1617

Serial No.: 10/762,714 Examiner: Claytor, Deirdre Renee

Filed: January 22, 2004

For: ANALGETIC DOSAGE FORMS THAT ARE RESISTANT TO PARENTERAL AND INHALATION DOSING AND HAVE REDUCED SIDE EFFECTS

New York, NY 10036
August 31, 2009

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

This is an appeal from he final rejection of all of the claims that was mailed March 12, 2009.

(i) *Real party in interest*. The real party in interest is Maxwell Gordon.

(ii) *Related appeals and interferences*. There are no related appeals or interferences.

(iii) *Status of claims*. Claims 1-6, 16-18 and 21-22 are the subject of this appeal. Claims 7-15 and 19-20 have been canceled.

(iv) *Status of amendments*. There are no unentered amendments.

(v) *Summary of claimed subject matter*.

Claim 1 is in independent form and it points out a solid pharmaceutical dosage form that contains an opiate, an opiate antagonist and an amount of hydrocolloid and other excipients, namely starch, lactose, xanthan gum, locust bean gum, monobasic calcium phosphate, dibasic calcium phosphate, microcrystalline cellulose, propylene glycol alginate, zein and magnesium stearate which are effective to form a viscous, non-injectable matrix when said dosage form is contacted with water. This claim defines a composition which is intended to be resistant to tampering so that one may not extract the opiate ingredient for abusive purposes.

Claims 2-4 are dependent on claim 1 and these claims point out specific preferred opiates and claim 5 points out naloxone as the preferred opiate antagonist.

Claim 6 is dependent on claim 1 and it points out a dosage form which has an enteric coated opiate antagonist which is effective to reduce or eliminate the constipating effects of specific opiates.

Claim 16 is in independent form and it points out a solid dosage formulation which has `pellets containing an opiate, an opiate antagonist, a hydrocolloid and excipients where one-third of the pellets are in immediate release form; one-third of the pellets are in delayed release form for release of the contents in the

jejunum and one-third of the pellets are in a delayed release form which releases in the ileum.

Claim 17 is dependent on claim 16 and it points out oxycodone as a preferred opiate and naloxone as a preferred antagonist.

Claim 21 is dependent on claim 1 and it points out preferred opiate antagonists.

Claim 18 is in independent form and it points out a method of preventing the formulation of a parenteral formulation of a solid dosage form of an opiate with a hydrocolloid which when in contact with water forms a viscous matrix which is too viscous to be injected with a hypodermic needle.

Claim 22 is in independent form and it points out a method for the treatment of constipation caused by opiates where enteric coated pellets of an opiate antagonist are administered to reduce or eliminate the constipating effect of specifically identified opiates.

(vi) (vi) *Grounds of rejection to be reviewed on appeal.*

Should the claims have been rejected under 35 U.S.C.§103(a)over Oshlack et al.(Oshlack) in view of Meissner.

(vii) *Argument.*

The Rejection Under Section 103

Claim 1 recites that the composition contains an opiate, and opiate antagonist and specific hydrocolloids. Claim 1 also recites that the ingredients are effective to form a viscous, non-injectable matrix when said dosage form is contacted with water. The claimed formulation has the property of forming a viscous composition when contacted with water so that it may not be injected and serve as a source of diverted opiates for use by intravenous drug abusers.

This specific formulation is not made obvious by Oshlack who mentions many formulations but none having the components of claim 1. The Oshlack invention is based on the use of sequestered aversive agents that impart a bitter, irritant or gelling effect when the dosage form is tampered with. If the dosage form is not tampered with, the aversive agent is not activated. An opiate antagonist that is sequestered or non-available may be added to prevent intravenous abuse but it has no role in reducing or preventing constipation. The use of an enteric coating agent is not disclosed or suggested by Oshlack. Since Oshlack teaches that the opiate antagonist should be sequestered so that it does not counteract the analgesic effect of the opioid (col. 3, lines 63-65). The composition of claim 1 cannot be made based on the teachings of Oshlack which does not teach a formulation which forms a viscous composition in contact with water. Some tampering is required to activate the Oshlack system.

Claim 6 recites a formulation where pellets containing

the opiate antagonist component are enteric coated pellets. The enteric coating controls the site of the release of the opiate antagonist and reduces or prevent the constipating effects of the opiate component. Claim 22 is a method claim which points out a method of reducing or preventing constipation where an opiate antgonist is administered in the form of enteric coated pellets in combination with an opiate and a hydrocolloid. Nothing in Oshlack or Meissner makes claim 22 obvious because Oshlack and or Meissner do not disclose an enteric coated formulation.

Independent claim 16 points out a specific formulation having three different pellets where the pellets are formulated so that one-third of the pellets are in immediate release form; one-third of the pellets are in delayed release form for release of the contents in the jejunum and one-third of the pellets are in a delayed release form which releases in the ileum. This concept is not in way suggested by the teachings of Oshlack or Meissner.

The Meissner reference recites that each patient must be titrated with the amount of naloxone antagonist to determine the dose for treating or preventing constipation. This makes each patient a research project and does not provide information as to how to make a dosage form. The claims of the present application point out that a viscous, non-injectable matrix, is formed when the dosage formulation is contacted with water.

The formulation of claim 16 releases the opiate antagonist at the termination end of the small intestine and in the large intestine and thus prevents constipation without the need to adjust or titrate the dose to experimentally determine what dose will prevent constipation.

The cited references do not make obvious the claimed composition and for these reasons, the rejection should be

reversed.

Respectfully submitted,

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(viii) *Claims appendix*

1. A solid pharmaceutical dosage form which comprises an opiate, an opiate antagonist and an amount of hydrocolloids and other excipients including starch, lactose, xanthan gum, locust bean gum, monobasic calcium phosphate, dibasic calcium phosphate, microcrystalline cellulose, propylene glycol alginate, zein and magnesium stearate which are effective to form a viscous, non-injectable matrix when said dosage form is contacted with water.

2. A solid pharmaceutical dosage form as defined in claim 1 wherein the opiate is elected from the group consisting of morphine, codeine, dilaudid, pantopon, methadone, paregoric, pentazocine, buprenorphine, fentanyl, oxycodone, oxymorphone, hydromorphone, hydrocodone, propoxyphene , nalbuphine and meperidine.

3. A solid pharmaceutical dosage form as defined in claim 2 wherein the opiate is oxycodone.

4. A solid pharmaceutical dosage form as defined in claim 1 wherein the opiate is oxycodone.

5. A solid pharmaceutical dosage form as defined in claim 4 wherein the opiate antagonist is naloxone.

6. A solid pharmaceutical dosage form as defined in claim 1 which includes an amount of enteric coated opiate antagonist pellets which is effective to reduce or eliminate the constipating effects of oycodone, methadone, morphine, codeine, dilaudid, pantopon, paregoric, pentazocine, buprenorphine, fentanyl, oxymorphone, hydromorphone, hydrocodone, propoxyphene , nalbuphine and meperidine.

7-15 (canceled)

16. A solid pharmaceutical dosage form which comprises a controlled release dosage form of an opiate, an opiate antagonist and a hydrocolloid and excipients as defined in claim 1, wherein said opiate, an opiate antagonist, hydrocolloid and excipients are formulated into pellets (a); pellets (b) and pellets (c);

pellets (a) comprise about one-third of said opiate, opiate antagonist and hydrocolloid in an immediate release form;

pellets (b) comprise about one-third of said opiate, opiate antagonist, hydrocolloid and excipients in an a delayed release form which releases substantially all contents of the pellets in the jejunum; and

pellets (c) comprise about one-third of said opiate, opiate antagonist, hydrocolloid and excipients in a delayed release form which substantially all of the contents of the pellets in the ileum.

17. A solid dosage form as defined in claim 16 wherein the opiate is oxycodone and the opiate antagonist is naloxone.

18. A method of preventing the formulation of an parenteral formulation of a solid oral dosage form of an opiate, said method comprising adding a hydrocolloid-excipient combination to a solid oral dosage formulation of an opiate so that when said solid oral dosage form contacts water, a matrix is formed which is too viscous to be injected via a hypodermic needle.

19-20 (canceled)

21. A solid pharmaceutical dosage form as defined in claim 1 wherein the opiate antagonist is selected from the group consisting of naloxone, naltrexone, methylnaltrexone and naloxonazine.

22. A method for the treatment of constipation caused by opiates which comprises administering a solid pharmaceutical dosage form as defined in claim 1 which includes an amount of enteric coated opiate antagonist pellets which is effective to reduce or eliminate the constipating effects of oycodone, methadone, morphine, codeine, dilaudid, pantopon, paregoric, pentazocine, buprenorphine, fentanyl, oxymorphone, hydromorphone, hydrocodone, propoxyphene , nalbuphine and meperidine.

(ix) *Evidence appendix.*

There is no evidencerelied upon in the appeandix

(x) *Related proceedings.*

There are no related proceedings